EXHIBIT 4

NOVARTIS

RESTRICTED

NTO CIMA APAC on behalf of GX XXGL - Sandoz Global QA

Audit ID No. 1443647

Final Report

Date: 27-Sep-2017

Audit Report

GMP, Routine

Zhejiang HuaHai Pharmaceutical Co.,Ltd.Chuannan site

Duqiao, Linhai, Zhejiang Province

317016, Zhejiang, China

GX, NTO - ESO,NTO - Solids

Audit Outcome:		Action Plan Due Date:
Satisfactory	19-Sep-2017 - 22-Sep-2017	**27-Oct-2017**

Purpose:

This was a routine GMP audit of Zhejiang Huahai Pharmaceuticals Co. Ltd. with the address of "Chuannan, Duqiao, Linhai, Zhejiang,317016" to assess process capability and GMP compliance against ICHQ7 and quality agreement signed between different Sandoz sites (Gebze-2 is the lead site) with Zhejiang Huahai Pharmaceuticals Co. Ltd Chuannan site applied to the manufacturing of non-sterile API listed in "Scope" section.

Scope:

Zhejiang Huahai Pharmaceuticals Co. Ltd. (hereinafter refers as Zhejiang Huahai Chuannan) is a pharmaceutical manufacturer for APIs and API intermediates This audit was focusing on Zhejiang Huahai Chuannan with the address "Chuannan, Duqiao, Linhai, Zhejiang, 317016".

APIs covered in this audit and the associated using sites are as below:

1) Redacted - Other Product(s)
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11
12) Valsartan (Commercial supply to Sandoz Kalwe)
13) Redacted - Other Product(s)

The audit was focused on the following:

a) Facility tour including raw material and final goods warehouse, production workshop and QC Laboratories

b) Product specific documents such as Annual product review for all the products listed above, completed Batch Manufacturing Record of products listed above, analytical record review of products listed above, analytical procedures, handling of reference substances, stability program for products listed above, OOS, deviation, change control, customer complaint and supplier qualification.

Note:
Redacted - Other Product(s)

Distribution List:

John Geissler, Isalia Leonardo, Nancy Fulginiti, Dipankar Kaul, Niamh Lynch, Achim Lueckel, Judita Fedija Sirca, Anton Kramaric, Elvide Atukeren, Acun Seda, Georges Ibrahim, Inci Civelek, Marlena Nowak, Piotr Lipinski, Vikram Pundir, Avinash Gode, Wolfram Schuetze, Frank Kuepker, Bill Zhu and Pinky Xu

Zhejiang Huahai Chuannan : Ms. He Yuelin, Ms. Wang Dongqin, Ms. Ge Jucai, Mr. Zhang Wei and Mr. Wang Peng.

Observation Overview:

	Major	Minor	Total
3.02 - GMP document and records management	0	1	1
3.11 - Stability Testing	0	1	1
6.05 - Production and Control	2	0	2
6.07 - Process Validation	0	1	1
Sum of Observations	2	3	5

Executive Summary:

This was a routine GMP audit and the focus was on the manufacturing process capabilities, implementation of quality systems and controls and review of data traceability and data reliability in quality control laboratory.

This audit was performed by 2 auditors over 4 days. The overall atmosphere was professional and site management shared the presentation pertaining to manufacturing, utilities, laboratory and material control related to the manufacturing of non-sterile APIs listed at "Scope" section. The discussion partners were found to be open and positive for suggestions. Most documents are written in Chinese language and assessment was conducted in Chinese language.

Positive aspect that was noted during the audit:

a) Clean and tidy facility
b) Good GMP knowledge among personnel
c) Overall sound GMP system implemented
d) Improvement from the last audit in September 2015

Zhejiang Huahai Chuannan site is regularly inspected by foreign regulatory authorities such as US FDA. The last US FDA audit was on May 2017 and 3 form 483s had been issued. Establishment Inspection Report (EIR) has been received. Zhejiang Huahai Chuannan had been also audited by CFDA (Aug 2016 and May 2017), Mexican Health Authority (COFEPRIS) on October 2016, German Hamburg Health Authority (BGV) on December 2016 and World Health Organization (WHO) on June 2017.

There is no Redacted - Other Product(s) being manufactured at Zhejiang Huahai Chuannan section. However, there is an oncology pilot plant workshop (W09) on the site but the workshop has not been in production for almost 2 years. Please refer to "Background" section for more details.

AUDIT OUTCOME

This audit has concluded that there is no significant finding which may have negative impact on the product quality of non- sterile APIs produced for Sandoz. Zhejiang Huahai Chuannan has the technical capability and a sufficiently good quality system to manufacture non-sterile APIs according to ICHQ7. Thus a "Satisfactory" rating is assigned.

There are 2 Major observations noted in this assessment as listed below. The observations are primarily related to improvements needed in some aspects of the quality systems, and do not directly impact the manufacturing process or product quality.

a) Deficiencies in the prevention of cross contamination between oncology workshop and other workshop as there was no access control installed at oncology workshop, swab for oncology residue did not extend to area beyond oncology workshop and risk assessment of manufacturing oncology product onsite did not cover QC lab.

b) Deficiencies in production practices where minor cleaning SOP for equipment batch to batch cleaning was not placed onsite, Redacted - Other Product(s)
Redacted - Other Product(s)

A CAPA plan is requested by Novartis/Sandoz to comply with the timescales of the Novartis/Sandoz quality system and should be submitted to the Lead Auditor in the required timeline; all observations cited in this assessment should be considered in a systematic way across all quality systems and stages of manufacturing and corrected in an appropriate time period according to their nature and severity.

Responsibility for Delivery of Action Plan:

The corrective and preventive actions should be defined and submitted to the Lead Auditor latest by the 27-Oct-2017.
After approval of the CAPA plan by the Lead Auditor, the corrective and preventive actions should then be updated whenever a CAPA is implemented or modified until all the CAPAs are successfully implemented.

Audit Team:

Lead Auditor:	Foo, Adrian - Regional QA Auditor
Supportive Auditor(s):	Xu, Pinky

Main Discussion Partners:

1) Ms. Ge Jucai
Title: Vice Plant Director (East Site)
Email: gejucai@huahaipharm.com

2) Mr. Wang Peng
Title: Executive Vice Plant Director (West Site)
Email: wangpeng@huahaipharm.com

3) Ms. Hu Yuelin
Title: QA manager (East site)
Email: huyuelin@huahaipharm.com

4) Ms. Wang Dongqin
Title: Assistant Quality director (West Site)
Email: wangdongqin@huahaipharm.com

5) Ms. Sophie Li
Title: Account Executive, Sales and Marketing
Email: lijurong@huahaipharm.com

Background Information:

Zhejiang Huahai Pharmaceutical Co., Ltd (hereafter called Zhejiang Huahai) was established in January 1989. It has become an integrated large-scale pharmaceutical manufacturing company in China with three manufacturing sites: Xunqiao site as company headquarter for manufacturing of FDFs and APIs; Chuannan site for manufacturing of APIs; and Huanan site for manufacturing pharmaceutical intermediates and starting materials. All the three sites are located in Taizhou city, Zhejiang China.

Zhejiang Huahai has 20 subsidiaries located in USA, Shanghai, Hangzhou, Jiangsu etc., and with full time employees over 4200 worldwide.

Zhejiang Huahai Chuanan is a pharmaceutical company specializing in the manufacturing of APIs and API intermediates. Zhejiang Huahai Chuannan has 2 zones, one is called as "East Zone" and one is called "West Zone". Both sections are under different management but under the same legal entity. Sandoz products are produced in both East and West Zones and this audit is focused on both sides of Zhejiang Huahai Chuannan. All manufacturing plants located at "West Zone" are denoted by a prefix of "W".

Zhejiang Huahai Chuannan site was established in year 2005. In total, there are a total of 1887 staff onsite for Zhejiang Huahai Chuannan in which 100 of them belonged to QA (46 personnel), QC (108 personnel).

PREVENTION OF CROSS CONTAMINATION BETWEEN ONCOLOGY AND OTHER PRODUCTS

W09 is a dedicated production plant for oncology products. The plant has not been in active production for almost 2 years. There are around 5 oncology products being manufactured in W09. There is a change room in the W09 and change to internal clothing including shoes before going to synthesis area. There is a dedicated clothes and gown washing facility onsite and dust generation room must be negative pressure compares to adjacent rooms and clean corridor to prevent cross contamination. Production personnel are also dedicated for the production of oncology products.

There was a risk assessment available for the manufacturing of oncology products in W09. There was an air sampling and swab exercise conducted onsite in year 2015 to test for the residue of oncology products onsite. Air sampling was performed on the HVAC exhaust and swab sample was performed on entrance of W09. This was the only oncology residue test exercise onsite as there was no production of oncology products taken place onsite.

List of documents reviewed:

1) Management regulations of measuring instruments (Document number: SOP CD-101-10)
2) Calibration procedure for temperature and humidity meter (Document number: Q/ZHH MLF-008-1)
3) Preventing management procedure of drug contamination and cross contamination (Document number: SOP DB-047-1)
4) Inactivation Management procedure of W09 workshop (Document number: SOP DB-048-1)
5) Risk assessment for Worskhop W09 (Document number: Workshop W09)
6) Access provisions of Workshop W09 synthetic area for personal (Document number: SOP DB-032-1)
7) Redacted - Other Product(s)
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18) Cleaning Expiry date Validation for facilities and Tools (Document number: CVA-15014)
19) Redacted - Other Product(s)
20) Risk assessment for equipment of Non-clean area of Workshop W05 (Document number: CERD-13-007)

21) Risk assessment for equipment of clean area of Workshop 05 (Document number: CERD-13-029)
22) Cleaning management program for Workshop W05 products (Document number: SOP DB-2217-4)
23) Redacted - Other Product(s)
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39) Purified water review for PW201 for year 2016 (Document number: ARD-PW-16-001)
40) HVAC review for W05 for year 2016 (Document number: ARD-HVAC-16-004)
41) Change control (Document number: ECRD-16001)
42) Management system of API material Supplier (Document number: SMP-015.07)
43) External audit plan (Document number: EAP-17-001)
44) Revalidation protocol of Nitrogen system (Document number: EQD-15063)
45) Periodic maintenance regulations on production equipment (Document number: SOP CD-017-8)
46) Regulation for recovered solvent (Document number: SOP CB-1732-4)
47) Redacted - Other Product(s)
48)
49) Corporate Documentation System (Document number: SMP-002.06)
50) Complaint management procedure (Document number: SMP-011.07)
51) Corrective and preventive Action (CAPA) Management System. (Document number: SMP-019.02)
52) Receiving records of materials for Aug-Sep 2017 (Document number: Q/ZCN JCG-037-7)
53) Approved Supplier List (Document number: Q/ZHH QA-039-2)
54) Sampling records of raw materials (Aug-Sep 2017) (Document number: Q/ZHH QC-032-4)
55) Redacted - Other Product(s)
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56)
57) Annual product review management system (Document number: SMP-020.05)
58) APR of Valsartan for 2016 for Workshop #2 (Document number: ARC-16-051)
59) Redacted - Other Product(s)
60) APR of Valsartan EU grade (code #C5355, EDMF and CEP) in workshop #2. (Document number: ARC-14-064)
61) Redacted - Other Product(s)
62)
63) VMP of Chuannan East Site (Document number: VMPC-15001)
64) Redacted - Other Product(s)
65) Batch records for Valsartan, #C5355-17-019M
66) Process validation for Valsartan (Document number: PVC-15032)
67) Redacted - Other Product(s)
68) Cleaning validation (API) SOP (Document number: SOP TE-001)
69) Cleaning re-validation of cleaning methods for Valsartan (Document number: CVC-16003)
70) Redacted - Other Product(s)
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73) Analytical method validation SOP (Document number: SOP QC-008)
74) Product release SOP (Document number: SMP-032.04)
75) Redacted - Other Product(s)
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Redacted - Other Product(s)

77) Redacted - Other Product(s)
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81) Training SOP (Document number: SMP-006.03)
82) Management procedure of job description (Document number: SOP HR-003)
83) Deviation SOP (Document number: SMP-017.04)
84) Change control SOP (Document number: SMP-018/04)

Lead Auditor:

Mr. Adrian Foo
Global Quality Assurance Audit & Compliance
20, Pasir Panjang Road,
#10-25/28, Mapletree Business City
Singapore, 117439
Tel: 65-67226405
Fax:65-68380818
Email: adrian-1.foo@sandoz.com

Support Auditor:

Ms. Pinky Xu
Global Quality Assurance Audit & Compliance
20, Pasir Panjang Road,
#10-25/28, Mapletree Business City
Singapore, 117439
Tel: 65-67226447
Fax:65-68380818
Email: pinky.xu@sandoz.com

Open Item from Previous Audit:

All CAPA actions noted in audit report#1601696 (conducted in April 2017) had been closed out except for observation#1604617 which is still in progress.

All CAPA actions noted in audit report #1340157 had been confirmed to have closed out.

ICH Chapter Comments:

01. CORPORATE QUALITY SYSTEM

REGULATORY INSPECTION

Zhejiang Huahai Chuannan site has been audited regularly by foreign regulatory body such as US FDA. The last US FDA audit was on May 2017 and 3 form 483s had been issued. Establishment Inspection Report (EIR) has been received. Zhejiang Huahai Chuannan had been also audited by CFDA (Aug 2016 and May 2017), Mexican Health Authority (COFEPRIS) on October 2016, German Hamburg Health Authority (BGV) on December 2016 and World Health Organization (WHO) on June 2017.

Zhejiang Huahai had passed all the audits above but they had not received GMP certificate from German Hamburg Health Authority (BGV) audit on December 2016 and World Health Organization (WHO) audit on June 2017

03. QUALITY AND COMPLIANCE SYSTEMS

SUPPLIER QUALIFICATION

Supplier qualification is found in place and governed by SMP-015.07, Management system of API material Supplier. Materials are categorized into different categories depending on their

criticality of use.

Materials that are categorized into critical materials are API Starting Materials (KSM), primary packaging material and solvents used in purification steps. Onsite audit is a must for primary packaging material, KSM supplier, hazardous materials that do not need to undergo QC testing, solvent used for purification but for supplier located outside China, it will be using either questionnaire audit or engage a 3rd party for audit. Audit frequency will be determined by the number of observations noted during onsite audit. If there is no onsite audit, then Zhejiang Huahai Chuannan will use risk assessment to review it.

Quality agreement (QAA) needs to be signed for suppliers for KSM, hazardous materials that do not need to undergo QC testing, solvent used for purification and primary packaging material. The KSM for Redacte Redacte Valsartan, Redacted - Other Product(s) are supplied by Huanan site. QAA between Huahai Chuannan and Huanan plant had been signed on 01 Nov 2014. The last audit was performed in 19-20 March 2015. CAPA plan had been received and closed out. Next audit will be in year 2018.

CUSTOMER COMPLAINT

Customer complaint is governed by Complaint management procedure (Document number: SMP-011.07). Sales department will receive the customer complaint and send it to relevant QA personnel. And a serial number will be assigned to the customer complaint. Preliminary assessment should be within 2 working days. A deviation will be raised if preliminary investigation has shown that it is due to Zhejiang Huahai's fault.

CAPA MANAGEMENT

CAPA management is governed by Corrective and preventive Action (CAPA) Management System. (Document number: SMP-019.02). CAPA process flow is as per the scheme below:

CAPA origin->Initiate CAPA->CAPA notification->CAPA implementation-> Close CAPA and archive-> CAPA effectiveness check and report.

Effectiveness check is a must for critical and major observations during audit. CAPA will be tracked by respective QA and remind CAPA responsible person on the due date. It will be tracked in quarterly quality meeting. CAPA effectiveness check will be performed during Q1 of the year.

DOCUMENTATION

Documentation is governed by Corporate Documentation System (Document number: SMP-002.06). Document preparation or revision is as per the scheme below:

Document preparation or revision-> Document numbering->document review-> document approval->document distribution->document training->Effective and execution->periodic review

3 layers of documentation classification:

1) Level 1 document is Standard Management Procedure (SMP)
2) Level 2 is SOP and quality standards
3) Level 3 is form, template and register

Periodic review is performed SMP is once every 2 years. Other documents will be once every 5 years

06. COMMERCIAL MANUFACTURING

WORKSHOP 03

Redacted - Other Product(s)

W03 is located at the West site of Huahai Chuannan and the whole site is accessed control and employee needs to swipe employee pass in order to go into production plant. Dispensing is performed in an enclosed room and dispensing tools are dedicated to products. Product code is engraved on the production tools. W03 is an enclosed workshop and all windows are equipped with window mesh to prevent the ingress of pest.

Redacted - Other Product(s)

Redacted - Other Product(s)

WORKSHOP 05

Redacted - Other Product(s)

Recycled solvent can only be used at the same production stage or the step before. Recovered solvent can only be used after QC testing. Material code is assigned to recovered solvent to prevent it to be used in other stages of production and also at different products.

Redacted - Other Product(s)

Redacted -

Redacted - Other Product(s)

Redacted - Other Product(s)

Redacted - Other Product(s)

Redacted - Other Product(s)

Redacted - Other Product(s)

Redacted -
Other

Redacted - Other Product(s)

VALSARTAN

Valsartan is manufactured at 3 production lines onsite i.e. Workshop 2, 12&13 and Workshop W02. These are all dedicated production plant for the manufacturing of Valsartan. There are 6 production steps involved in the manufacturing of Valsartan. Step 1 to Step 3 are involved in the manufacturing of intermediates and Step 4 is the manufacturing of Crude Valsartan. Step 5 is the final purification step and Step 6 is the packaging step. Step 5 and 6 are taken place in ISO 8 cleanroom.

Recycle solvent is used in the manufacturing of Valsartan.

Ethyl Acetate is the crystallization solvent at the purification stage. It will be packaged in PE bag placed in aluminum bag, heat sealed and placed in fiber drum. There is no special storage condition for the final product of Valsartan.

Redacted - Other Product(s)

Redacted - Other Product(s)

Redacted - Other Product(s)

UTILITIES

WATER SYSTEM

Purified water (PW) system PW201 was visited. This purified water system supplies purified water that satisfies CP, USP and EP grade purified water to Workshop W02, W05, W08 and W10 in Zhejiang Huahai Chuannan. Production of purified water is as the scheme below:

[redacted]

Distribution system will be sanitized using steam [redacted]C for [redacted]. Water velocity from the return loop is monitored. It has been noted that all PW user points in W05 is monitored for endotoxin test. (Specification is ≤0.25EU/ml).

HVAC

HVAC system is responsible to maintain the intended cleanliness class for all ISO 8 cleanroom onsite. Differential pressure between primary and secondary filter is monitored regularly. All ISO 8 cleanroom onsite has a temperature and humidity specification of [redacted]°C and [redacted]%RH.

They will perform settling microbial count (TAMC≤100 and TYMC≤20), active air sampling (TAMC≤100 and TYMC≤20) and contact plate (TAMC≤50 and TYMC≤20). Environmental monitoring will be tested [redacted] for critical rooms (room with product exposure) and [redacted] for settling microbial count. For non-critical room, environmental monitoring is performed [redacted] and for settling microbial count. It is conducted [redacted].

Leak test for HEPA filter will be performed [redacted] using PAO method.

NITROGEN GAS

Nitrogen gas is used [redacted]

[redacted]

They will test nitrogen gas for particle size, total microbial count≤100cfu/m3, water (≤100mg/m3) and oil content (≤1ppm) [redacted].

WAREHOUSE

There is no ERP system being deployed in the warehouses of Zhejiang Huahai Chuannan site. Incoming goods receipt is performed at which visual inspection and surface cleaning of incoming goods are performed. Warehouse is managed by manual system in terms of approval status, inventory control, storage location and First in first out (FIFO).

Warehouses is access control and only accessible by warehouse personnel. A copy of approved vendor list is available in the warehouse in shared drive and also in hardcopy format. Incoming goods will be placed under "Quarantine" after unloading. "Quarantine" status is denoted by yellow color whereas "Approved" status is denoted by green color. Reject room is available.

It has been noted that all incoming materials will be issued with a new in-house batch number upon receipt. Temperature and humidity for final product storage is controlled at [redacted]°C and [redacted]%RH.

Sampling operation is conducted in a sampling room located in warehouse. Sampling room is constructed with surfaces that are easy to clean.

07. ANALYTICS AND TESTING

QC LABORATORIES

QC laboratory is consolidated for both East Zone and West Zone at Chuannan site. The QC laboratory is used for testing of raw materials, intermediates, and finished goods from both manufacturing zones. There are 2 QC labs onsite. One is located at the "East Zone" and one is located at "West Zone".

In East Zone, QC lab has 3 levels. For Level 1, it is used for raw material and intermediate testing. Retention sample room is also located at Level I. Level II is for Wet chemistry testing, HPLC testing for final products. For Level III, there is a microbiology lab available. Stability chambers and also reference standard storage are also located at Level III.

There is no LIMS available in QC lab. All instruments in the lab are complied with the requirement of 21 CFR Part 11. Audit trail is available for all QC instruments and it will be reviewed at every batch release using a checklist. All balances are equipped with printers. The entire QC lab is access control and entry will be using employee pass scan.

In West Zone, QC lab is located at Level I. All GC, KF and PSD tests are performed in this QC lab. Similar to the QC lab at East Zone, all instruments in the lab are complied with the requirement of 21 CFR Part 11.

Microbiology laboratory – Microbiology laboratory is located at Level III of East Zone QC lab. All incubators are continuously monitored via temperature printout. Audio alarm is also available and alarm is connected to guard house. Growth promotion test is performed for every prepared media. Reconciliation of media usage is also tracked.

There are 2 autoclaves available, one is for destruction and one is for sterilization.

Observations:

3 - Quality and Compliance Systems

Unique QA issuance serial number was not assigned to equipment PM record — ID No. 1648925 — Minor

Quality Module: 3.02 - GMP document and records management
Quality System: 02 - Quality Assurance / Compliance
Quality Sub System: 2.09 - Document Management, Archiving

Observation Description
Ensure that unique QA issuance number is assigned to Equipment preventive maintenance record (Document number: Q/ZCN JCD-01401).

No QA issued serial number was assigned to Equipment preventive maintenance record (Document number: Q/ZCN JCD-01401□to prevent unauthorized replacement of pages.

Observation Comment
Note: This is a one time observation and this observation is not systemic and the site has a good record management and QA serial number is stamped in all records reviewed. Thus it is rated as "Minor"

Action Required: Yes

Intermediate hold time determination was not performed as per the worst temperature scenario of the year — ID No. 1648915 — Minor

Quality Module: 3.11 - Stability Testing
Quality System: 06 - Laboratory Systems And Controls
Quality Sub System: 6.10 - Stability

Observation Description
Ensure that hold time determination was performed similar to the worst temperature scenario of the year

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Redacted - Other Product(s)

6 - Commercial Manufacturing

Deficiencies in the prevention of oncology products and non-oncology products — ID No. 1648913 — Major

Quality Module: 6.05 - Production and Control
Quality System: 10 - Production Practices And Controls
Quality Sub System: 10.04 - Production Practices and Procedures

Observation Description
Ensure that prevention of cross contamination measures between oncology workshop W09 and other workshops are robust.

a) External packaging surface of container that contains oncology products is only wiped with ethanol, no exact deactivation media was mentioned in Prevention management procedure of drug contamination and cross contamination (Document number: SOP DB-047-1)
b) There is no air shower/mist shower for personnel when coming out from the dust generation area in Workshop W09
c) Risk assessment for Workshop W09 does not cover the scenario of oncology products testing in the QC lab.
d) Swab test for oncology residue was not performed on other area including the air intake point at adjacent manufacturing blocks, canteen and QC lab
e) There is no access control mechanism being installed at Workshop W09 to control entry from unauthorized and untrained personnel into oncology workshop.

Observation Comment
Note: There had been no production activities for Workshop W09 for almost 2 years.

Action Required: Yes

Non compliance of production practices against GMP requirement — ID No. 1648927 — Major

Quality Module: 6.05 - Production and Control
Quality System: 10 - Production Practices And Controls
Quality Sub System: 10.04 - Production Practices and Procedures

Observation Description
Ensure that production practices and workshop condition complies with GMP requirement.

1) Workshop W05:

Redacted - Other Product(s)

b) PE bag used in cleanroom of W05 does not have a 'Product Label"(Document number: Q/ZHH PR-027-3) that should be pasted so that the batch number of the PE bag can be known.

(Note: It was noted that an inventory card carrying all the information is placed next to the pile of PE bag but 'Product Label" should be pasted on the exterior as per Huahai's procedure.)

2) Workshop W18 Redacted -

Redacted - Other Product(s)

Action Required: Yes

Type of process validation (PV) was not written in PV protocols ID No. 1648917 Minor

Quality Module: 6.07 - Process Validation
Quality System: 09 - Validation
Quality Sub System: 9.05 - Process Validation

Observation Description
Ensure that types of process validation(PV) are written clearly in process validation protocol.

Redacted - Other Product(s)

Observation Comment
Note: Zhejiang Huahai Chuannan personnel had mentioned that PV conducted onsite should be prospective PV.

Action Required: Yes

Note
It must be emphasized, however, that auditing is a sampling process and that these non-conformances may not reflect all those that need attention. Full compliance with current requirements through regular self-inspections should be the company's objective.

The observations and comments shown on this report have been approved in the system by:

Person Name / Function	ID	Date / Time
Audit Report Completed By		
Foo, Adrian Regional QA Auditor	FOOAD2	27-Sep-2017 01:53 PM (GMT-02:00)
Audit Report Approved By		
Sundstroem, Erika	SUNDSER1	27-Sep-2017 09:13 PM (GMT-02:00)